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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,586	08/08/2005	Masaru Nakatani	81844.0053	9941

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HOGAN & HARTSON L.L.P.
1999 AVENUE OF THE STARS
SUITE 1400
LOS ANGELES, CA 90067

EXAMINER	
CHRISTIAN, MARJORIE ELLEN	
ART UNIT	**PAPER NUMBER**
1797	
MAIL DATE	**DELIVERY MODE**
05/15/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/516,586	NAKATANI ET AL.	
	Examiner	Art Unit	
	MARJORIE CHRISTIAN	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/12/2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment filed 3/12/2009 has been entered and fully considered.

2. The information disclosure statement filed 8/8/2005 has been fully considered.

3. Claims 1-18 are pending and have been fully considered.

Double Patenting

4. Claims 1-3, 6-7, 9, 16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5-7, 9-11 of copending Application No. 11/718,386. Although the conflicting claims are not identical, they are not patentably distinct from each other because both disclose blood contact material with tryptophan and dextran sulfate.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

5. **Claims 1-7, 9-18 are rejected under 35 U.S.C. 103(a) as obvious over JP07-136256, INAMA et al. (hereinafter INAMA) as evidenced by US Patent No. 4, 576, 928, TANI et al. (hereinafter TANI).**

As to Claims 1-3, 9, INAMA discloses an adsorbent capable of whole blood treatment for adsorbing low-density lipoproteins and fibrinogen (INAMA,

Claim 1), comprising: tryptophan (Pg. 7, Para. 17) and a polyanionic compound (Pg. 7, Para. 17) which are immobilized on a water-insoluble porous carrier (Pg. 5, Para. 13). INAMA also recognizes optimizing the amount of polyanionic compound and tryptophan to improve the performance of the adsorbent (Pg. 3, Para. 9 & Pg. 5, Para. 14), where it would naturally flow to have an amount of the immobilized polyanionic compound in the range of 0.10-1.5 μmol/mL of wet volume of the adsorbent, as evidenced by TANI (C7/L27-35). INAMA does not expressly disclose the molar ratio of tryptophan to polyanionic compound of 1 to 70. However, it has been held that discovery of an optimum value of a result effective variable is ordinarily within the skill of the art. *In re Boesch and Slaney, 205 USPQ 214 (CCPA 1980); In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977)*; "[W[here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (MPEP 2144.05, II)*.

As to Claim 2, INAMA discloses that the polyanionic compound is dextran sulfate (Pg. 7, Para. 18).

As to Claim 4, 10-12, INAMA discloses the water-insoluble porous carrier is cellulose (Pg. 4, Para. 12).

As to Claim 5, 13-15, INAMA discloses the water-insoluble porous carrier has a molecular weight exclusion limit of $5x10^5$ to $1x10^8$ for globular proteins (Pg. 4, Para. 11).

As to Claim 6, 16, INAMA discloses a method comprising bringing the adsorbent according to claim 1 or 5 (see 103(a) rejections of Claims 1, 5) into contact with a body fluid containing low-density lipoproteins and fibrinogen (Pg. 1, Para. 1).

As to Claim 7, 17-18, INAMA discloses an adsorber comprising: a container having a fluid inlet, fluid outlet and means for preventing an outflow of an adsorbent to the outside (Pg. 3, Para. 7), the container is filled with the adsorbent according to claims 1, 5 or 6 (see 103(a) rejections of Claims 1, 5, 6).

6. **Claim 8 is rejected under 35 USC 103 (a) as being obvious over JP07-136256, INAMA et al. (hereinafter INAMA) in view of US Patent No. 5,286,449, KURODA et al. (hereinafter '449) as evidenced by US Patent No. 4, 576, 928, TANI et al. (hereinafter TANI).**

As to Claim 8, INAMA discloses the adsorbent as shown in the 103(a) rejections of Claims 1, 7. INAMA does not appear to expressly disclose the capacity of the adsorber. However, '449 discloses the capacity of the adsorber is 100 ml to 400 ml (C16/L25).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the adsorber of INAMA to include the capacity of the adsorber of '449. The motivation would have been to stably conduct whole blood treatment with a decreased blood volume being taken outside the body (C16/L25-31). Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

7. **Claims 1-4, 6-12, 18 are rejected under 35 USC 103 (a) as being obvious over US Patent No. 5,286,449, KURODA et al. (hereinafter '449) as evidenced by US Patent No. 4,576,928, TANI et al. (hereinafter TANI).**

As to Claims 1-3, 9, '449 discloses an adsorbent capable of whole blood treatment for adsorbing low-density lipoproteins and other malignant components of whole blood (C17/L45-50, C5/L39-43), comprising tryptophan (C10/L7) and dextran sulfate (C8/L54-60) which are immobilized on a water-insoluble porous carrier (C6/L44-59). '449 also recognizes optimizing the amount of polyanionic compound and tryptophan to improve the performance of the adsorbent (C10/L9-65), where it would naturally flow to have an amount of the immobilized polyanionic compound in the range of 0.10-1.5 μmol/mL of wet volume of the adsorbent, as evidenced by TANI (C7/L27-35). '449 does not expressly disclose the molar ratio of tryptophan to polyanionic compound of 1 to 70. However, it has been held that discovery of an optimum value of a result effective variable is ordinarily within the skill of the art. *In re Boesch and Slaney, 205 USPQ 214 (CCPA 1980); In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977)*; *In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (MPEP 2144.05, II)*.

As to Claim 4, 10-12, '449 discloses the water-insoluble porous carrier is a cellulose carrier (Claim 9).

As to Claim 6, '449 discloses a method comprising bringing the adsorbent according to claim 1 (refer to 103(a) rejection of Claim 1) into contact with a body fluid containing low-density lipoproteins and fibrinogen (Examples 1-5).

As to Claim 7, 18, '449 discloses an adsorber (Fig. 1), comprising a container having a fluid inlet (2), fluid outlet (3), and means for preventing an outflow of an adsorbent to the outside (C4/L1-18), the container is filled with the adsorbent (1) according to claim 1, 6 (refer to 103(a) rejection of Claims 1, 6).

As to Claim 8, '449 discloses the capacity of the adsorber is 100 ml to 400 ml (C16/L25).

8. **Claims 5, 13-17 are rejected under 35 USC 103 (a) as being obvious over US Patent No. 5,286,449, KURODA et al. (hereinafter '449) as evidenced by US Patent No. 4,576,928, TANI et al. (hereinafter TANI) and US Patent No. 4,627,915, KURODA et al. (hereinafter '915).**

As to Claim 5, 13-15, '449 discloses the same water-insoluble porous carrier ('449, Claim 9), where it is inherent that since the carrier is the same then it also has a molecular weight exclusion limit of $5x10^5$ to $1x10^8$ for globular proteins, as further evidenced by '915 (C7/L20-22).

As to Claim 16, '449 discloses a method comprising bringing the adsorbent according to claim 5 (see 103(a) rejection of claim 5) into contact with a body fluid containing low-density lipoproteins and fibrinogen (Examples 1-5).

As to Claim 17, '449 discloses an adsorber (Fig. 1), comprising a container having a fluid inlet (2), fluid outlet (3), and means for preventing an outflow of an adsorbent to the outside (C4/L1-18), the container is filled with the adsorbent (1) according to claim 5.

9. **Claims 1-6, 9-16 are rejected under 35 USC 103 (a) as being obvious over US Patent No. 4,576,928, TANI et al. (hereinafter TANI).**

As to Claims 1-3, 9, TANI discloses an adsorbent capable of whole blood treatment for adsorbing low-density lipoproteins and fibrinogen (Abstract), comprising tryptophan (C5/L9) and dextran sulfate which are immobilized on a water-insoluble porous carrier (C7/L23-25), wherein the amount of the immobilized polyanionic compound is 0.10-1.5 μmol/mL of wet volume of the adsorbent (C7/L27-35). TANI also discloses optimizing the amount and mixture of ligands used (C5/L24-25, C6/L8-14 & C7/L23-25). TANI does not expressly disclose the molar ratio of tryptophan to polyanionic compound of 1 to 70. However, it has been held that discovery of an optimum value of a result effective variable is ordinarily within the skill of the art. *In re Boesch and Slaney, 205 USPQ 214 (CCPA 1980); In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977)*; *In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (MPEP 2144.05, II)*.

As to Claim 2, TANI discloses that the polyanionic compound is dextran sulfate (C5/L45).

As to Claim 4, 10-12, TANI discloses the water-insoluble porous carrier is cellulose (C7/L14-15).

As to Claim 5, 13-15, TANI discloses the water-insoluble porous carrier has a molecular weight exclusion limit of $5x10^5$ to $1x10^8$ for globular proteins (C7/L41-42).

As to Claim 6, 16, TANI discloses a method comprising bringing the adsorbent according to claim 1 or 5 (see 103(a) rejections of Claims 1, 5) into contact with a body fluid containing low-density lipoproteins and fibrinogen (Abstract).

10. **Claims 7-8, 17-18 are rejected under 35 USC 103 (a) as being obvious over US Patent No. 4, 576, 928, TANI et al. (hereinafter TANI) in view of US Patent No. 5,286,449, KURODA et al. (hereinafter '449).**

As to Claim 7, 17-18, TANI discloses the adsorbent according to claim 1, 5 or 6 (see 103(a) rejections of Claims 1, 5-6). TANI does not appear to expressly disclose a container with inlet, outlet and means for preventing outflow of the adsorbent. However, '449 discloses a container having a fluid inlet (2), fluid outlet (3), and means for preventing an outflow of an adsorbent to the outside (C4/L1-18).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the adsorbent of TANI to include the container of '449. The motivation would have been to have a module for whole blood treatment that is efficient and effective so that malignant components of blood can be removed (C1/L30-35). Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

As to Claim 8, '449 discloses the capacity of the adsorber is 100 ml to 400 ml (C16/L25).

Response to Arguments

11. Applicant's arguments filed 3/12/2009 have been fully considered but they are not persuasive. Applicant argues that the references INAMA, TANI and KURODA ('449) do not render the molar ratio of immobilized tryptophan and immobilized polyanionic compound obvious.

For the purposes of clarification, Example 2 of KURODA ('449) (which incorporates Example 1), demonstrates that the concentrations of tryptophan and dextran influence the efficiency of adsorption. TANI discloses inclusion of tryptophan in the adsorber and polyanionic compounds to optimize removal of various compounds (as shown above). INAMA discloses the addition of tryptophan and negative functional groups in an adsorber to improve adsorption of LDL, VLDL and fibrinogen (Pg. 7, Para. 17).

Applicant's arguments are not found persuasive as it is known by a person having ordinary skill in the art that the amount of tryptophan and polyanionic compound present effect the adsorbent's ability to efficiently adsorb components in a whole blood treatment and it would be obvious to a person with ordinary skill to optimize their concentrations to improve performance. Specifying the amount of tryptophan and polyanionic compound present as a molar ratio does not patentably distinguish from the prior art as it is well known to optimize result effective variables and optimization (by specifying the molar ratio) does not appear to demonstrate any unexpected results. The molar ratio does not structurally differentiate the apparatus from the prior art, as the prior art optimizes

the concentrations of tryptophan and polyanionic compound to improve the removal of undesirable components from blood.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARJORIE CHRISTIAN whose telephone number is (571)270-5544. The examiner can normally be reached on Monday through Thursday 7-5pm (Fridays off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571)272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MC

/Krishnan S Menon/

Primary Examiner, Art Unit 1797